SUBJECT:

Review of Supplemental Request to Duke University Grant RD833293 Children's Center Grant, Southern Center on Environmentally-Driven

Disparities in Birth Outcomes

FROM:

April Richards

TO:

Nigel Fields



(b) (4), (b) (5)



NICHOLAS SCHOOL OF THE ENVIRONMENT DUKE UNIVERSITY

CHILDREN'S ENVIRONMENTAL HEALTH INITIATIVE
Maria Lynn Mirondo, PhD • Director

September 28, 2009

Mr. Nigel Fields Environmental Protection Agency USEPA Headquarters 1200 Pennsylvania Avenue, N. W. Washington, DC 20460

Dear Mr. Fields:

Enclosed please find a report on the Community Assessment Project undertaken by the Children's Environmental Health Initiative (CEHI) at Duke University in collaboration with community partners in Durham. The purpose of the project is to better understand the relationship between environment and health and to disseminate results to the community. Given your important efforts to enhance quality of life in our community, we thought you would find this report interesting and relevant.

During the summer months of 2008, CEHI conducted a visual survey in Central Durham neighborhoods to document aspects of the "built environment." The built environment includes the landscape that is created by human development (e.g., houses, buildings, streets, sidewalks). We assessed, from the public right-of-way, the features that define the physical environment in which we all live. This report describes the Community Assessment Project and shows sample maps summarizing the data collected during the assessment, as well as demographic information and public safety data. We hope this report, along with the associated website (http://cehi.env.duke.edu/cap/), will be useful tools to community members and stakeholders.

We hope to work closely with community organizations like yours in identifying ways that the Community Assessment Project can support efforts to enhance quality of life in Durham. Please feel free to contact us if you would like additional information on the report or the associated website.





To: Cc: "Pamela Maxson, Ph.D." <pamela.maxson@duke.edu>,

Bcc:

Subject: Re: SAC information

Excellent, Pam, thank you.

Rich

Rich Callan **Environmental Health Scientist** U.S. Environmental Protection Agency ORD, National Center for Environmental Research

"Pamela Maxson, Ph.D."

Hi Rich, I'm sorry I was delayed on this. N...

03/17/2011 02:30:30 PM

From:

"Pamela Maxson, Ph.D." <pamela.maxson@duke.edu>

To:

Richard Callan/DC/USEPA/US@EPA

Date:

03/17/2011 02:30 PM

Subject:

SAC information

Hi Rich,

I'm sorry I was delayed on this. No excuse- it just slipped down my list.

Our SAC members are: Gayle Harris gharris@ph.co.durham.nc.us Ian Gilmour.ian@epamail.epa.gov Jason Moore Jason.h.moore@dartmouth.edu Jay Kaufman jay kaufman@unc.edu Philip Landrigan phil.landrigan@mssm.edu Sudipto Banerjee baner009@umn.edu

We met with them in December of 2009. We are planning a retreat with them in the fall of 2011, although we do not have dates yet.

Please let me know if I can be of any further assistance.

Thanks, Pam

Pamela J. Maxson, Ph.D. Research Director Director of Human Resources Children's Environmental Health Initiative Box 90328, A135A LSRC Duke University (919) 812-8389 pm12@duke.edu



Re: New Subcontract Request for Duke Children's Center (RD83329301)



Richard Callan to: Roberto Perez

08/30/2011 06:39 PM

Cc: Nica Louie, "Jennifer Robbins", Devon Payne-Sturges

Thank you, Roberto. I will contact Joselynn Hawkins at GIAMD. That's a good point about Marie Lynn being a UM employee since her salary will now be paid from there.

I also went back and checked on the date -- as I thought, Marie Lynn originally told me, and the press release from UM confirmed it, that her appointment would be effective January 1, 2012, this is the first notification I've received that the date was changed.

I will ask them to send a revised budget and justifications as you suggest for the remaining funds. They are already in Year 5 and all of their incrementals have already been paid. Should they use the SF424A form?

I'm not sure how they would compete the subcontracted work since they want to use that mechanism to pay for employees who are already on staff, just to shift the payroll to UM. Could you please advise us on that -- can they write a justification for why those positions will not be competed?

In terms of percent effort, the original proposal said

so I've asked them if that will

change as well.

Rich

Roberto Perez

You may first need to discuss this with GIAMD t ...

08/30/2011 05:34:51 PM

From:

Roberto Perez/DC/USEPA/US

To:

Richard Callan/DC/USEPA/US@EPA

Cc:

Nica Louie/DC/USEPA/US@EPA, "Jennifer Robbins" < Robbins. Jennifer@epamail.epa.gov>

08/30/2011 05:34 PM

Date: Subject:

Re: New Subcontract Request for Duke Children's Center (RD83329301)

You may first need to discuss this with GIAMD to see if the current arrangement with the Pl listed as the lead can remain unchanged if she is moving to another institution. Don't know if the Duke faculty appointment matters if she will now be an employee of UM. Once that matter is resolved we can see how to proceed. with the PI. Regardless, we'll need an explanation of the circumstances surrounding the change.

We'll also need revised budgets and budget justifications. Costs associated with the staff would be a "subaward" with the charges included in the OTHER budget category. Remember that subcontracts are generally for services, not for Co-PI involvement and they need to be competed by the recipient. The recipient should also state that the scope of work remains unchanged along with the total project cost.

rp

From: Richard Callan

Sent: 08/30/2011 10:08 AM EDT

To: Roberto Perez Cc: Nica Louie

Subject: Fw: New Subcontract Request for Duke Children's Center (RD83329301)

Hi Roberto,

Marie Lynn Miranda, the PI of the Duke Children's Center, is is moving to the University of Michigan (UM) as of September 1st. (I think the date she originally gave me was January 1st 2012 so I guess they decided to move up the timetable.) She will continue to have a faculty appointment at Duke and plans to remain as PI. I have asked them whether she will still maintain the same percent effort on the grant and expect to hear back this week. Her salary will now be paid by UM.

Some of her staff will also be paid by UM so Duke wants to issue a subcontract for that work.

Could you please advise as to the procedure for them to get the subcontract approved as part of the Center grant, and any other forms or procedures that are necessary on our end? Thank you for your help with this.

--Rich

From: Keith Hurka-Owen [kpho@duke.edu]

Sent: 08/29/2011 09:08 PM GMT

To: Richard Callan; Devon Payne-Sturges; Nica Louie

Cc: "Marie Lynn Miranda, Ph.D." <mmiranda@duke.edu>; David Bynum <david.bynum@duke.edu>;

"auten001@mc.duke.edu" <auten001@mc.duke.edu>; Joselynn Hawkins

Subject: Subcontract Request

Dear Rich, Devon, and Nica,

As you are aware, Dr. Marie Lynn Miranda has accepted a position at the University of Michigan (UM), effective 1 September 2011. Dr. Miranda will maintain a faculty appointment and PI status at Duke, which will allow her to remain as Principal Investigator on the Southern Center on Environmentally Driven Disparities in Birth Outcomes (SCEDDBO; RD-83329301). She has made arrangements with and received assurances from the provost at the University of Michigan, including infrastructure, that she can continue her research program. Dr. Miranda plans to focus her research efforts on children's environmental health and geospatial informatics. Thus she will have a smaller research program, but one where SCEDDBO lies at its very heart.

We do not anticipate problems in managing the grant between these two institutions as Dr. Miranda will be spending significant time each month in North Carolina, with monthly in-person center investigator meetings continuing uninterrupted. In addition, video- and tele-conferencing infrastructure have already been established to advance the work of the individual projects on a day-to-day basis. We emphasize that Dr. Miranda currently successfully collaborates with researchers in Kenya, Uganda, and Tanzania, where the communications infrastructure is not as strong as we have here in the United States.

Some of the technical staff from Project A and the Geographic Information Systems and Statistical Analysis (GISSA) Core will become employees of UM. In addition, 100% of Dr. Miranda's salary will be paid by UM. Thus we write to request that the USEPA allow Duke University to issue a subcontract to UM to cover those SCEDDBO-related activities that will now be carried out by UM employees.

We appreciate your consideration of our request,

Marie Lynn Miranda, Ph.D
Director, Children's Environmental Health Initiative
Professor, Nicholas School of the Environment and Department of Pediatrics
Box 90328
Duke University
Durham, NC 27708
919-613-8723 (o)
919-684-3227 (fax)
mmiranda@duke.edu
www.nicholas.duke.edu/cehi



Keith Hurka-Owen, Director Office of Research Support Duke University 2200 West Main St., Suite 710 Campus Box 104010 Durham, NC 27705-4677

Ph.: 919-681-8687 FAX: 919-684-2418



Fw: Subcontract Request for Duke Children's Center (RD83329301/Miranda)

Richard Callan to: Joselynn Hawkins Cc: Roberto Perez, Jennifer Robbins

08/30/2011 06:58 PM

Hi, Joselynn,

The PI of the Duke Children's Center (EPA STAR Grant RD83329301), Marie Lynn Miranda, is moving to another institution. As of September 1st, 2011, she will start a new faculty position at the University of Michigan (UM) and her salary will be paid 100% from that institution. However, she will maintain a faculty appointment at Duke University and would like to remain as PI of the Duke Children's Center. All of the incrementals have been paid for the grant, which is scheduled to close on 4/30/2012, but they will likely apply for a no-cost extension.

I'm the NCER project officer for this grant and would like to find out if the current arrangement, with Dr. Miranda listed as the PI can remain unchanged if she is moving to another institution. I understand that we will need an explanation of the circumstances for the change of institution, a new budget and budget

They also want to keep the same set of employees but since some of them will now be paid by UM, they want to issue a subcontract for that work (please see their email below).

If you could please advise us as to the next steps, then I'll get back in touch with Duke and the PI and let them know how we should proceed.

Thank you,

Rich

Rich Callan, MPH **Environmental Health Scientist** Health Research and Fellowships Division ORD, National Center for Environmental Research U.S. Environmental Protection Agency Phone: 703-347-8051 Fax: 703-347-8140

Office Address for FedEx, Express Mail or Courier: US EPA, 2777 South Crystal Drive (Potomac Yard One), Room S-11937, Arlington, VA 22202

Mailing Address (can take a month for delivery): 1200 Pennsylvania Avenue NW, Mail Code 8723P, Washington, D.C. 20460-0001

National Center for Environmental Research http://www.epa.gov/ncer/

----- Forwarded by Richard Callan/DC/USEPA/US on 08/30/2011 06:46 PM -----

From:

Keith Hurka-Owen <kpho@duke.edu>

To:

Richard Callan/DC/USEPA/US@EPA, Devon Payne-Sturges/DC/USEPA/US@EPA, Nica

Louie/DC/USEPA/US@EPA

Cc:

"Marie Lynn Miranda, Ph.D." <mmiranda@duke.edu>, David Bynum <david.bynum@duke.edu>,

"auten001@mc.duke.edu" <auten001@mc.duke.edu>, Joselynn Hawkins/DC/USEPA/US@EPA

Date:

08/29/2011 05:08 PM

Subject:

Subcontract Request

Dear Rich, Devon, and Nica,

As you are aware, Dr. Marie Lynn Miranda has accepted a position at the University of Michigan (UM), effective 1 September 2011. Dr. Miranda will maintain a faculty appointment and PI status at Duke, which will allow her to remain as Principal Investigator on the Southern Center on Environmentally Driven Disparities in Birth Outcomes (SCEDDBO; RD-83329301). She has made arrangements with and received assurances from the provost at the University of Michigan, including infrastructure, that she can continue her research program. Dr. Miranda plans to focus her research efforts on children's environmental health and geospatial informatics. Thus she will have a smaller research program, but one where SCEDDBO lies at its very heart.

We do not anticipate problems in managing the grant between these two institutions as Dr. Miranda will be spending significant time each month in North Carolina, with monthly in-person center investigator meetings continuing uninterrupted. In addition, video- and tele-conferencing infrastructure have already been established to advance the work of the individual projects on a day-to-day basis. We emphasize that Dr. Miranda currently successfully collaborates with researchers in Kenya, Uganda, and Tanzania, where the communications infrastructure is not as strong as we have here in the United States.

Some of the technical staff from Project A and the Geographic Information Systems and Statistical Analysis (GISSA) Core will become employees of UM. In addition, 100% of Dr. Miranda's salary will be paid by UM. Thus we write to request that the USEPA allow Duke University to issue a subcontract to UM to cover those SCEDDBO-related activities that will now be carried out by UM employees.

We appreciate your consideration of our request,

Sincerely,

Marie Lynn Miranda, Ph.D
Director, Children's Environmental Health Initiative
Professor, Nicholas School of the Environment and Department of Pediatrics
Box 90328
Duke University
Durham, NC 27708
919-613-8723 (o)
919-684-3227 (fax)
mmiranda@duke.edu
www.nicholas.duke.edu/cehi



Keith Hurka-Owen, Director Office of Research Support Duke University 2200 West Main St., Suite 710 Campus Box 104010 Durham, NC 27705-4677

Ph.: 919-681-8687 FAX: 919-684-2418 Received 10/7/2011 M



Allison Ashley-Koch, Ph. D. Associate Professor

Rich Callan, Ph.D.
Environmental Health Scientist
Health Research and Fellowships Division ORD,
National Center for Environmental Research
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW, Mail Code 8723P
Washington, D.C. 20460-0001
Phone: 703-347-8051

Dear Rich-

I am writing to you to request approval to use funds from Dr. Marie Lynn Miranda's program project grant to attend the International Congress of Human Genetics in Montreal, Quebec, Canada for the dates of October 11 through the 15. As you know, we have three poster presentations that I will be presenting on behalf of our Children's Center. I have estimated the total cost for me to attend at \$2500. This includes \$1000 for hotel, \$450 for registration fees, \$550 for flight and \$500 food. I certainly appreciate any consideration EPA gives for this approval.

Sincerely,

(b) (6)

Allison Ashley-Koch, Ph.D. Associate Professor Center for Human Genetics Duke University Medical Center



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF RESEARCH AND DEVELOPMENT

MEMORANDUM

October 7th, 2011

SUBJECT: Request to the Office of International Activities/Department of State for

Clearance on International Research and Travel Activities for Assistance

Agreement No. RD83329301, Duke

FROM: Richard Callan (8723P)

Project Officer, National Center for Environmental Research

Office of Research and Development

TO Vanessa Fleeton (2680R)

Office of International and Tribal Affairs

Attached is a request for Allison Ashley-Koch, Associate Professor, Center for Human Genetics at Duke University Medical Center, to receive permission to travel to the International Congress of Human Genetics conference in Montreal, Canada and have her travel expenses paid from EPA STAR Grant #RD83329301. The grant is to the Duke University Children's Environmental Health and Disease Prevention Research Center, the PI is Marie Lynn Miranda, and Professor Ashley-Koch is an investigator on the grant. Professor Ashley-Koch is presenting three poster presentations at the conference on behalf of the Center. To attend the 5-day conference, she has estimated the cost at \$1000 for the hotel room, \$450 for registration fees, \$550 for her air travel and \$500 for meals, for a total of \$2500. Funds were budgeted in the grant proposal for travel for presentations at scientific meetings.

The objective of the Southern Center on Environmentally-Driven Disparities in Birth Outcomes (SCEDDBO) is to determine how environmental, social, and host factors jointly drive health disparities and birth outcomes. The Center is supporting the following three highly integrated studies: (1) a geographic information system based, statistics project; (2) a community-based birth cohort; and (3) a basic science animal model project.

Here is the information requested by OITA:

- 1. Project ID number: RD83329301
- 2. Name of recipient: Duke University
- 3. EPA Project Officer: Richard Callan, (703) 347-8051, callan.richard@epa.gov
- 4. Project Title and Description: Southern Center on Environmentally Driven Disparities in Birth Outcomes
- 5. Budget and project periods: 05/01/2007 04/30/2012 (same dates for both budget and project periods)

- 6. The proposal is being sent via email.
- 7. Itemized budget:
- \$11,500/year was budgeted in the grant for travel in years 4 and 5 of the grant which includes presentations at conferences. International travel is requested in the following amounts: \$2500 to attend the International Congress of Human Genetics, which includes \$1000 for hotel expenses, \$450 for registration fees, \$550 for air travel and \$500 for food expenses.
- 8. Country where foreign travel/work is taking place: Canada
- 9. Statutory authorities:

Clean Air Act: Sec. 103; Clean Water Act: Sec. 104; Safe Drinking Water Act: Sec. 1442; National Environmental Policy Act-Section 102(2)(F). When used in conjunction with EPA's authorizing statutes, Section 102(2)(F) of the National Environmental Policy Act (NEPA) authorizes support to foreign recipients and foreign work/travel by domestic recipients. This statutory authority is being cited to cover travel to and work in Canada.

- 10. Agency Strategic Goal: This Center supports Goal 4, Health Communities and Ecosystems, and Objective 4.4, Enhance Science and Research.
- 11. Program Results Code: 404FB2DPV
- 12. A link to the signed IGMS funding recommendation is provided in the email accompanying this memo.



Re: OITA Approval Needed for Grantee Travel next week -- is that possible?

Vanessa Fleeton to: Richard Callan

Cc: Iris Zeigler

10/07/2011 11:00 AM

History:

This message has been replied to.

Richard,

Send me the request and I'll try my best to get it approved quickly. Normally we ask that requestor's to give at least two weeks notice because you take a chance of not getting approved in time for your trip. Please advise traveller for future requests.

Thanks.

Vanessa Fleeton EPA/Office of International & Tribal Affairs Office of Management & International Services

Mailcode: 2680R Phone: (202) 564-4762 Fax: (202) 565-8074

Richard Callan

Hi Ms. Fleeton, I got a message from the grante...

10/07/2011 10:04:22 AM

From:

Richard Callan/DC/USEPA/US

To:

Vanessa Fleeton/DC/USEPA/US@EPA

Cc:

Iris Zeigler/DC/USEPA/US@EPA

Date:

10/07/2011 10:04 AM

Subject:

Re: OITA Approval Needed for Grantee Travel next week -- is that possible?

Hi Ms. Fleeton,

I got a message from the grantee saying she still has to attend the conference in Canada to give her presentation. She will be there through next Friday. If we submit the request to DOS today, and it is approved next Friday, would it be OK for her to charge at least some of the expenses for the trip from Friday and the rest of the conference travel to the grant?

Thank you,

Rich

Vanessa Fleeton

---- Original Message ----

From: Vanessa Fleeton

Sent: 10/06/2011 05:27 PM EDT

To: Richard Callan Cc: Iris Zeigler

Subject: Re: OITA Approval Needed for Grantee Travel next week -- is that

possible?

I forwarded your request asking Iris if there is any other way. Next Fri, Oct. 14 is the earliest I can approve. 5 bus. days.

I'm ccing Iris on this e-mail also.

Thanks,

Vanessa Fleeton EPA/Office of International & Tribal Affairs Office of Management & International Services Mailcode: 2680R

Phone: (202) 564-4762 Fax: (202) 565-8074



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF INTERNATIONAL AND TRIBAL AFFAIRS

OFFICE OF INTERNATIONAL AND TRIBAL AFFAIRS (OITA) AND **DEPARTMENT OF STATE (DOS)** CLEARANCE

Clearance is required for any	Domestic or international awards	for assistance agreements	which include foreign	or international components
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Recipient:

Duke University

Project Title: Purpose of trip: To attend the International Congress of Huamn Genetics conference from

Oct. 11-15, 2011. Travel costs \$2500.

Project Dollar Amount: \$11,500.00. 7,735, 637.00

Notes:

To ascertain project benefit to any existing or proposed formal or informal intergovernmental arrangement

- EPA's overall relationship with the country concerned is coordinated and aligned

-Proposed activity as stated in the statement of work advances the Agency's Strategic Goals in advancing

public health and environment improvement

EPA Program	Office/Mail	Code:	ORD	/8723
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EPA Contact / Phone Number:	Richard Callan / 703-347-8051	.41.1.
OIA Program Office Clearance:	- I was how a	Date: 10/7/11
	Steven Wiener / Program Officer	
	(b) (6)	1 1
	Mighael M. Stahl / Deputy Assistant Admin	Date: /0/1/1/
LON-1	Mighael M. Stahl / Deputy Assistant Admin	istrator, OITA
D		/
Date Submitted to DOS: 10	1-7-11	
DOS Contact Person: Mari	a Urbina	
	f, Central Programming Unit, Office of E	xecutive Director, OES/EX

(Clearance assumed within 5 working days, unless otherwise noted by DOS)

		For Internal Use Only	
Vanessa Fleeton	(b) (6)	Pate:	10-14-11



Re: PI for EPA STAR grant RD83329301(Duke University/Miranda) changing institutions -- PI and subaward questions

Joselynn Hawkins to: Richard Callan

10/31/2011 01:58 PM

History:

This message has been replied to and forwarded.

Hi Richard,

It is okay for her to remain as the PI, as long as Duke University is aware that they are still responsible for the management of the grant. We will need a revised budget for the subaward, and I will issue an amendment to reflect the change in budget due to the PI changing institutions so that we have a paper trail of the change.

I hope this answers everything but let me know if you still have questions.

Thanks,
Joselynn Hawkins, Grants Specialist
U.S. EPA, OARM, GAD
1200 Pennsylvania Avenue, N.W. 3903R
Washington, D.C. 20460

Phone: 202-564-5305 Fax: 202-565-3082

Richard Callan

Hi Joselynn, I hope all is well with you. I have b...

10/28/2011 01:44:48 PM

From:

Richard Callan/DC/USEPA/US

To:

Joselynn Hawkins/DC/USEPA/US@EPA

Date:

10/28/2011 01:44 PM

Subject:

PI for EPA STAR grant RD83329301(Duke University/Miranda) changing institutions -- PI and

subaward questions

Hi Joselynn,

I hope all is well with you. I have been notified that Marie Lynn Miranda, who is the PI for the Duke University Children's Center (EPA STAR Grant RD83329301), will be moving from Duke University to the University of Michigan. However, she will also be keeping a faculty appointment at Duke. Could you please let me know, is it OK with GIAMD that she would still remain as the PI of the Center since she will still have the Duke appointment? They have told us that 100% of her salary will be paid by the University of Michigan and not by Duke.

Some of Marie Lynn's technical and support staff are moving with her and will become employees of the University of Michigan so we will need to do a subaward for those expenses that are shifted over. They are already in Year 5 of a 5-year grant and all of their incrementals have been paid. So we would not be issuing any additional award documents for this grant -- it will just be shifting some of the funds to a subaward.

Could you please let me know how I should proceed with this? Do I just need to ask them for a revised budget for the costs being shifted to the subaward? Thank you!

Best	regard	S.

-	-		
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г	NI.		

Duke CEHC subcontract to UM Miranda, Marie Lynn to: Richard Callan, Nica Louie 01/02/2012 01:18 PM

"pm12@duke.edu", "'Richard Auten (auten@duke.edu)'", "Crary, Kathryn" Show Details

Hey Rich and Nica,

As you know, I officially started as dean at SNRE at UM on January 1st. It's an exciting time for me, but I remain fully committed to the work of SCEDDBO. I am attaching, per your request, a statement of work and a budget justification for the subcontract we would like Duke to issue to the University of Michigan. As you will see from the attached documents, most of the SCEDDBO funds will remain at Duke. The transfer of funds for GIS analysts and statisticians, however, is crucial to our continued success. Please let me know if you require any additional information from us.

Also, FYI, we will be requesting a 1 year no cost extension on our award. Our current contract goes through 4/30/2012. Because of the gap in funding created by the timing of the RFA, we believe it prudent to request a no cost extension. Can you let us know what we need to do to make that happen?

With all best wishes for health and happiness in the new year.

mlm

Marie Lynn Miranda, Ph.D
Director, Children's Environmental Health Initiative
Professor, School of Natural Resources and Environment and Department of Pediatrics
2046 Dana Building
440 Church Street
University of Michigan
Ann Arbor, MI 48109
734.764.2550 (o)
mlmirand@umich.edu





Re: Duke CEHC subaward to the University of Michigan (EPA STAR Grant RD83329301)

Richard Callan to: Miranda, Marie Lynn

01/06/2012 03:26 PM

"'Richard Auten (auten@duke.edu)", "Crary, Kathryn", Nica Louie, Cc: "pm12@duke.edu", Joselynn Hawkins

Hi Marie Lynn.

Happy New Year and congratulations on beginning your exciting new position as dean of the School of Natural Resources and Environment (SNRE) at the University of Michigan (UM)!

Thank you for sending these documents for your move to a new institution for the Duke University Children's Center (EPA STAR Grant RD83329301). Duke University needs to be aware that they are still responsible for management of the grant. Note that we consider funds going to another academic institution to be a subaward and not a subcontract. For the UM subaward, then, we should have a separate subaward package including a budget justification which would cover only the UM expenses and a revised budget for the subaward with a breakdown in table format of exactly how the funds will be used, just as you would provide for a subaward as part of the original application. You could use the NIH PHS 398 form page 5 for this as was provided in the original application (see link below) PHS 398 Form Page 5: Budget for Entire Proposed Project Period MS Word (86 KB) PDF (573 KB)

Do you think you could send the package to us by February 1st? Then I can forward those documents to Joselynn Hawkins in the Grants and Interagency Agreement Management Division who will prepare an amendment to document the change.

For the no-cost extension you just need to let me know at least 30 days before the date the grant is scheduled to close that you want the extension. Are you certain that 1 year will be sufficient to complete all of the original aims in your proposal, data analysis and submit all of the manuscripts for publication? I would suggest that you consider requesting a 2-year no-cost extension to provide additional time to complete your data analysis and prepare manuscripts for publication, because it is generally more difficult to get approval for an additional extension after the first one has been granted. Just let me know what you would prefer. In any case, I will need a letter documenting the request and the reason the extension is needed. I would be happy to speak with you about this before you prepare the letter if that would be helpful.

Best wishes to you and your colleagues for a healthy and happy 2012!

Warm regards	5,
--------------	----

Rich

Rich Callan, MPH **Environmental Health Scientist** Health Research and Fellowships Division ORD, National Center for Environmental Research U.S. Environmental Protection Agency Phone: 703-347-8051 Fax: 703-347-8140

Office Address for FedEx, Express Mail or Courier: US EPA, 2777 South Crystal Drive (Potomac Yard One), Room S-11937, Arlington, VA 22202 Mailing Address (can take a month for delivery): 1200 Pennsylvania Avenue NW, Mail Code 8723P, Washington, D.C. 20460-0001 National Center for Environmental Research http://www.epa.gov/ncer/

18 March 2012

Mr. Richard Callan 1200 Pennsylvania Avenue NW Mail Code 8723F Washington, DC 20460

Dear Rich:

I write to request a no-cost extension on the grant that funds our Southern Center on Environmentally-Driven Disparities in Birth Outcomes (SCEDDBO, RD83329301). The current end date on the grant is 30 April 2012. We would like to request a two-year no-cost extension on the grant. The no-cost extension is required to allow us to complete the specific aims of the original proposal.

SCEDDBO leverages and promotes active partnerships among the Nicholas School of the Environment, the Duke University Medical Center, Trinity College of Arts and Sciences, the Children's Environmental Health Initiative (CEHI), as well as the Durham County Health Department (DCHD), and the Lincoln Community Health Center (LCHC). CEHI has recently moved its headquarters from Duke to the University of Michigan. SCEDDBO brings together the expertise of obstetricians, pediatricians, genetic epidemiologists, spatial statisticians, environmental scientists, social epidemiologists, social psychologists, geographers, and community organizations. While SCEDDBO has been very productive since funding began on 1 May 2007, work remains to be done, as we are at a critical point in our efforts to understand environmental contributors to disparities in pregnancy outcomes.

Below, I detail, by component of the center, why a no-cost extension is required and what that extension will allow us to accomplish.

Administrative Core

If the other components of SCEDDBO are still operational, then it will be critical to maintain the activities of the administrative core. This core ensures that cross-component communication is active and timely. In addition, our Young Investigators Program would continue to support the career development of young scientists. Interrupting the mentorship and support provided by the Young Investigators Program would compromise our objective to bring on board the next generation of environmental health scientists. This would also allow us to bring together the

External Science Advisory Board (we have been unable to find a time when all board members are available before the end of the grant award).

Project A: Mapping Disparities in Birth Outcomes

The central objective of Project A is to determine whether and to what extent joint exposures to socioeconomic and environmental stressors contribute to racial and ethnic health disparities in poor pregnancy outcomes. As part of SCEDDBO's work, we obtained and geocoded the detailed birth record data from 1990-2008. We have also obtained the 2009 data, which was not available until mid-2011. These data have now been processed, but still need to be geocoded. The additional year of the birth record data are necessary as key environmental exposure variables which we would like to assess for association with pregnancy outcomes, are richer and more detailed for more recent years. So the robustness of our analyses requires this additional work. In fact, if granted the no-cost extension, we would obtain the 2010 birth record data and geocode it as well, as this would allow us to achieve our original specific aims of assessing the impact of environmental exposures on pregnancy outcomes.

Substantial effort has been devoted to assessment of the effects of the *built environment* on adverse pregnancy outcomes. Built environment attributes have been collected through the Community Assessment Project (part of the work of our Community Outreach and Translation Core). These built environment data have been linked with the NC DBR 2008 data to examine the social and environmental influences on birth outcomes. We are now using spatial statistics and other methods to assess the impact of the built environment on pregnancy outcomes. Preliminary results show a connection between the built environment and pre-term birth and low birth weight. To achieve the original specific aims of this project, we need to do additional statistical analysis on the built environment data. We also need to look at changes between the 2008 and 2011 built environment data and whether changes in the built environment are reflected in changing pregnancy outcomes. We plan to correlate the 2008 and 2011 CAP data and maternal and infant health.

In addition, achieving a better understanding of exposure to air pollution, particularly particulate matter and ozone, is a central focus of our future efforts. We recently began the process of linking participants in Project B with their associated birth certificate record. This linkage, which is not yet complete, will allow us to assess data accuracy in the detailed birth record and validate the newly developed methods of synthesizing categorical data. We have also very recently received data on air toxins from the USEPA and still need to assess the relationship between these environmental exposures and pregnancy outcomes in order to fulfill the original specific aims of the project.

Project B: Healthy Pregnancy, Healthy Baby: Studying Racial Disparities in Birth Outcomes

Participant Recruitment. For Project B, we continued recruiting participants through summer 2011 (final N = 1860). The dataset has now been finalized, after entry and subsequent QA/QC of the data. We are now well-situated to take full advantage of the psychosocial, genetic, and

environmental data that we have spent over four years collecting. In order to fully exploit these data, we request additional time to run analyses and prepare manuscripts. Community Assessment Project/Built Environment. An important measure of potential environmental stress is the built environment. Our 2008 CAP assessed built environment variables for over 17,000 tax parcels, including the home addresses of over 40% of the participants in the Healthy Pregnancy, Healthy Baby Study (SCEDDBO Project B). Analyses of this built environment data are underway. Seven scales (housing damage, property disorder, security measures, tenure, vacancy, violent crime and nuisances) have been constructed at five levels of geography (census block, primary adjacency communities, census block group, census tract, and city-defined neighborhoods). The variables have been linked with the Durham birth records (Project A) and with the clinical OB participants' records (Project B), which enables multiple analyses of the relationships among the built environment, psychosocial health, and pregnancy outcomes. The second phase of data collection was completed in year 5, with 30,700 tax parcels assessed, bringing our Project B participant capture rate to 70%. We are in the process of compiling results and disseminating the information to the community, an integral component of our Community Outreach and Translation Core. In addition, we plan to connect the CAP data with the psychosocial, genetic, and physical health of mothers and infants in the Clinical OB project. Further, we have longitudinal data on 17,000 tax parcels and would like to explore change and stability in the built environment. All of these efforts are required for us to meet the original specific aims of the proposal.

Genetic analysis. We are currently working on statistical methods development for high-dimensional genetic and clinical data in the Healthy Pregnancy, Healthy Baby cohort. This has been extremely complicated work, and we require additional time to achieve the original specific aims of the project focused on gene x environment interactions.

Statistical methods innovation. We have made advances on innovative data analytic techniques and further statistical methods innovation. We require additional time to exploit computational resources in order to complete studies devoted to high-number dimensional reduction. This is required to achieve our overall goal, which is to characterize and understand the complex interactions amongst the three categories of factors that we hypothesize influence pregnancy outcomes: host, social, and environmental contributors. With the completion of the final dataset, we can pursue this overarching goal once the novel statistical methods have been validated.

Project C: Perinatal Environmental Exposure Disparity and Neonatal Respiratory Health We have made considerable progress in all Aims of this component, demonstrating that maternal inhalational exposure to both industrial air pollutant PM and diesel exhaust worsen the effects of postnatal ozone on both airway hyperreactivity (asthma model) and on lung alveolar structure. These 'priming' effects have demonstrable changes in fetal inflammatory responses which persist to juvenile stages. In order to better understand the maternal component of this effect (Specific Aim 2), we have conducted studies in mice deficient in Toll-like receptor 4 (TLR4), an important component of innate immune responses. For practical reasons, our proof-of-principle studies that exposed pregnant mice to diesel exhaust at environmentally relevant concentrations (collaborator, Dr. Ian Gilmour, U.S. E.P.A., Research Triangle Park, NC) were transitioned to diesel exhaust particle aspiration because of competing biodiesel studies in the U.S. EPA exposure facilities. Our studies showed that intermittent exposure during

pregnancy to diesel exhaust (or to oropharyngeal aspiration of collected diesel exhaust particles) augmented the effects of postnatal ozone exposure on airway hyperresponsiveness and on the impairment of alveolar development (Auten *et al.* (2012) *Am J Resp Crit Care Med*). We have determined that these inflammatory responses lead to long-term increased susceptibility to pulmonary immune challenge in offspring and that this effect is heritable, likely *via* epigenetic mechanisms. In order to determine the window of vulnerability during pregnancy and the nature of the time-specific responses to environmentally relevant concentrations of diesel exhaust, we require additional studies using the real-time diesel exhaust that we are arranging now, but which cannot be scheduled or analyzed within the original project period. We note that these additional studies are required for us to complete the original specific aims of the proposal.

In Specific Aim 4, we seek to determine whether genetic or developmental susceptibility to airway hyperreactivity exacerbates maternal and/or postnatal exposure effects on postnatal somatic and lung development/function. We found that innate immune responses are required for the maternal inflammatory responses to diesel exhaust to be transduced to fetal tissues: pregnant mice lacking TLR4 can still mount an inflammatory response to inhaled diesel, but the fetuses must have intact TLR4 signaling to mount a response. Furthermore, this signaling pathway is required in offspring for the development of ozone-induced airway hyperreactivity. We have made the novel observation that chronic ozone exposure in newborns has effects on airway hyperreactivity in adults (asthma model) that depend on interaction of inflammatory responses with neural responses (specifically, the efferent M2 muscarinic receptor). This observation has important implications for how air pollution exposure during early life increases life-long vulnerability to asthma. In order to complete these studies, we require additional time to perform analysis on materials we have collected to assess effects of the altered immune response pathways (host susceptibility) on postnatal lung structure and function. These additional studies are required for us to complete the original specific aims of the proposal.

Cross Project

We are working on manuscripts describing the synergies between our three projects, including air pollution and the social context of environmental influences. These collaborative efforts will require additional time to complete.

The entire SCEDDBO team prioritized air pollution as one of the primary environmental contaminants to be examined across projects. This has involved significant discussions between members of Project B with members in Project A to construct viable markers of air pollution, including proximity to major roadways, and NATA data. Project B also prioritized the interleukin/inflammatory genes for analysis after consultation with Project C so that we could make more biological synergies across the two projects. Similarly, Project C introduced a nest-deprivation model into the ongoing animal experiments in an attempt to better model the more complex psycho-social stressors that were identified as influential factors for human subjects enrolled in Project B. Bringing together the collective insights to be garnered from the air pollution work across all three projects is critical to achieving the original specific aims of the proposal.

We have similar cross-project work and manuscripts that are only now coming to fruition in the areas of statistical methods development, the built environment, and the social context of environmental exposures.

Community Outreach and Translation Core

Disseminating the Community Assessment Project wave 2 results is an integral component of our COTC. We are finalizing our 2012 report, which translates the results in an easily accessible format. We plan on widely disseminating this report throughout the Durham community through community meetings. The process of staying engaged with communities takes time. We did not want to begin the active phase of the dissemination process for the 2012 report until community groups indicated that they were positioned and had time to work with us. We felt it was important to be respectful of the many demands on our community partners. So the no-cost extension is critical to achieving the original specific aims of the project.

In addition, we are collaborating with the Duke School of Nursing to integrate environmental education into the nursing curriculum. The curriculum will educate nurses on environmental exposures and maternal and child health outcomes. The School of Nursing needed more time before modules could be incorporated into the curriculum. We anticipate active collaboration during the 2012-2013 academic year – again necessitating the no-cost extension to complete the original specific aims of the project.

Geographic Information System and Statistical Analysis (GISSA) Core

The GISSA Core is integral to the functioning of all three research projects, as well as the Community Outreach and Translation Core. So if these other components of SCEDDBO are functioning, we need the GISSA Core functioning as well. In particular, the GISSA Core will improve the data architecture required for Projects A and B above, process the 2009 birth records, obtain and process the 2010 birth records, refine the environmental exposure data layers, and support the statistical analyses described above. All of these activities are required to achieve the original specific aims of the project.

Please let me know if you have any questions or concerns about this request for a no-cost extension. Thank you for your consideration.

Sincerely,



Marie Lynn Miranda, Ph.D.

Cc: Richard Auten, Kathleen Crary, Klugh Jordan, Pamela Maxson